# BIOSTATISTICS

*with Professor Sumithra J. Mandrekar and Professor Jay N. Mandrekar*

## Talking *points*

**KNOWLEDGE**

1. What is biostatistics?
2. What data do researchers collect during clinical trials?

**COMPREHENSION**

3. Why is it necessary to conduct a clinical trial before a new medical intervention is used?
4. How do biostatisticians contribute to clinical trials?
5. How are some cancer treatments becoming more personalised?

**APPLICATION**

6. If you were collecting data for a clinical trial of a new drug to treat arthritis, what variables would you want to record from participants before, during and after the trial?
7. How do you think biostatisticians contribute to the field of epidemiology (the study of diseases in populations)?

**ANALYSIS**

8. It might be assumed that more detailed surveys lead to better information. Why do you think that Jay's much shorter questionnaire led to more reliable conclusions?
9. Why do you think that collaboration with other health scientists is such an important part of Sumithra and Jay's work?

**EVALUATION**

10. Clinical trials involve significant ethical considerations. How do you think clinical trial designs account for:
    - Risk of serious side effects of the new intervention
    - Some patients not having the opportunity to receive the new, and potentially better, intervention and so not personally benefitting from their involvement in the trial
    - Privacy concerns about patients' personal data
    - Disruption of patients' lives to gather data

## Activity

Imagine you are a biostatistician. You have been asked to design a clinical trial to test one of the following:

- A test to screen for a specific type of breast cancer
- A drug that may relieve symptoms of bipolar disorder
- A psychiatric technique that may help people recovering from alcohol addiction

Sumithra notes it is important for biostatisticians to have a good knowledge of the biological aspects of their work. Therefore, as a first step, research your chosen condition using the internet. Look for answers to questions such as:

- What are the symptoms?
- What are existing treatments?
- How does the condition affect quality of life?
- How many people does the condition affect?

Once you have completed your research, design your clinical trial. Think about:

- Experimental design: Who will you recruit as participants in the trial? What interventions will different groups of participants receive? What outcomes will you measure on the participants in the trial? How long will the trial run for?
- Variables: What data will you collect before, during and after the trial?
- Results: How will you use the data to draw conclusions about the intervention's effectiveness? How will you handle the data analysis if some participants leave the study before its completed? What results would indicate the intervention is of benefit to the participants?
- Ethical considerations: How will you ensure participants are safe, have a good quality of life and are informed about the trial goals and the data that will be collected on them?

As a final step, pair up with a classmate. One of you take on the role of researcher while the other takes on the role of a participant. Explain your clinical trial to them and what they should expect as a participant. Answer any questions they may have. Then, swap roles and listen to their explanation about the trial they have designed.

## More *resources*

- This video from Mayo Clinic, where Sumithra and Jay work, gives an accessible overview of clinical trials and why they are important: www.youtube.com/watch?v=iWqQiJeP5ac
- This article from Statology uses interesting examples to explain the importance of statistics in healthcare: www.statology.org/importance-of-statistics-in-healthcare
- Visit the NIH clinical trials website to discover the range of trials that are currently happening around the world: www.clinicaltrials.gov/ct2/home